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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/08/2003

*20*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/269,999

Applicant(s)

SMITH ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-37 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of request for extension of time (granted) and amendment both filed 12-23-02 is acknowledged. Claim 21 has been amended as requested and claims 21-37 are pending.

### ***Election/Restrictions***

1. This application contains claims 20 and 37 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the requirement that the porous articles have "predetermined" levels of porosity. The specification shows that porosity level is controlled, but does not provide support that the porosity level is known prior to making the article. The specification states that the cell/foam structure of the articles is influenced by the length

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of time before polymerization starts. However, the specification reasonably convey how the length of this time affects the foam structure (i.e. "x" number of minutes results in a particular percentage porosity). In other words, the specification does not convey a specific amount of time resulting in a predicted amount or level of porosity.

***Response to Arguments***

4. Applicant's arguments filed 12-23-02 have been fully considered but they are not persuasive. Applicant's comments that page 9 of the instant specification discloses that the pore sizes in the formed article can be controlled to yield a porosity range from about 20% to about 95% are noted, however Applicant has not addressed the relationship between time and the resultant particular percentage porosity. Applicant states that the length of time before polymerization starts can be controlled between an instantaneous polymerization and one which starts after a period (up to twenty minutes or more) and that the specification discloses that this period has a major influence on cell structure where the porous article is to be used as a bone substitute. However, Applicant does not point out where the specification discloses the length of this time that affects the foam structure to result in a particular percentage porosity. Accordingly, the rejection is maintained.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 21-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The instant claims require formation of a porous article having a predetermined level of porosity, however, the instant claims do not set forth the parameters for achieving the predetermined level of porosity. In other words, the claim requires a predetermined level of porosity, but then fails to establish the parameters to achieve the level that is predetermined. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

#### ***Response to Arguments***

8. Applicant's arguments filed 12-23-02 have been fully considered but they are not persuasive. Applicant argues that the instant claims set forth the parameters for achieving the predetermined level of porosity in that instant claim 21 recites adding a surfactant, introducing small bubbles of oxygen containing gas into the dispersion with agitation for form a foam which is allowed or caused to coalesce, and adjusting the period from the formation of the foam to the start of the polymerization by adding initiator and catalyst at rates selected to influence the structure of the pores to be present in the porous article and that claim 21 requires that the porous article has a porosity of between 20% and 95% with pore walls and struts defining pores of pore sizes in the range of 15 to 150  $\mu\text{m}$ . Applicant then states that another factor that influences the growth of the foam structure and therefore the level of porosity is the period before the onset of polymerization which can be an instantaneous polymerization

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and one which starts after a period (up to 20 minutes or more). However, Applicant does not set forth the confines of this period of time and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 21-29, 31-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sambrook et al (WO 93/04013; hereafter '013).

'013 discloses all the limitations of the instant claims. See the abstract and page 7, line 4 - page 8, line 13 and examples. The pore sizes are disclosed as being dependant on the filter (page 7, last two lines). Filter sizes are then discloses in the examples as being 10-16 microns. Also, Example VIII discloses that the mean pore diameter is 24 microns. Controlling the polymerization rate is disclosed at the bottom of page 11).

### ***Response to Arguments***

11. Applicant's arguments filed 12-23-02 have been fully considered but they are not persuasive. Applicant argues that '013 does not disclose the same method "consisting essentially" of the features recited in the instant claims. Most notably, Applicant asserts that '013 does not teach the internal pore structure of the article formed and that it does

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not teach controlling the rate of polymerization. Regarding the former, it appears Applicant is asserting that '013 does not disclose the porosity and size of the pores as required in the instant claims. Page 11, lines 7-8 and the examples of '013 disclose that the porosity ranges from about 20% to about 95% and the sizes of the resulting pores are within the instant claimed range. Regarding controlling the rate of polymerization, page 9, lines 23-27, page 11, lines 14-25 and example IX of '013 discloses addition of initiator and catalyst for pore formation. Applicant asserts that example IX of '013 results in settling of the solids and therefore affects the interior structure of the finally formed article. However, no data providing evidence to this assertion has been provided and Applicant's comments are therefore deemed speculative.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 21- 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013).

'013 teaches all the limitations of the instant claims. '013 does not specify pore sizes greater than 150 microns. '013 does teach adjustment of the pore size through choice of filter, drying under reduced pressure, which causes the foam to expand, or adjusting the speed of stirring when introducing the gas bubbles. Accordingly,

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adjustment of the pore size would be obvious to one skilled in the art at the time of the invention according to the nature of the intended article (i.e. impregnation of the pores with agents). Firing the solid article at 1350° C is disclosed in '013 and results in a final pore size within the instant range. Thus, firing the solid article at 1250° C does not appear to be critical as the same final pore size appears to be achieved. Controlling the polymerization rate is disclosed at the bottom of page 11).

### ***Response to Arguments***

14. Applicant's arguments filed 12-23-02 have been fully considered but they are not persuasive. Applicant's response to the rejection under 35 U.S.C. 102(b) are reiterated for that under 35 U.S.C. 103(a) and therefore the response to these arguments are again relied upon here. Since they have been set forth *supra* paragraph 11, they are not repeated here.

15. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013) in view of Takagi et al (US 4,654,314; hereafter '314) or vice versa.

'013 is relied upon for all that it teaches as stated previously. '013 does not specifically state including the subsequent step of growing bone cells in the porous ceramic product. '013 does state that the products are useful for artificial parts for the body.

'314 is relied upon for teaching that artificial parts comprising growth of bone cells in ceramic products is known. '314 also teaches that the pores of the ceramic



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product should be between 1 and 600  $\mu\text{m}$  to promote induction of "new-born bone" and turnover of a bone while keeping a good compatibility with a living body.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to incorporate bone cells into the invention of '013 with the motivation of using the ceramic products as artificial parts comprising growth of bone cells and the expectation that the products would be useful for inducing new-born bone, controlling resorption of bone with age, and remedying bone defects.

Also, it would have been obvious to one skilled in the art at the time of the invention to incorporate the invention of '013 into the teachings of '314 as the method of making the ceramic products and the resulting products of '013 may be made more quickly, with better mechanical strength and handling and machining characteristics.

### ***Response to Arguments***

16. Applicant's arguments filed 12-23-02 have been fully considered but they are not persuasive. Applicant argues that there would be no motivation to combine '013 and '314 since they approach a method in two different ways. This argument is not completely clear. In the event Applicant is arguing that the references are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both references are within the field of Applicant's endeavor in that both references and Applicant is concerned with porous ceramic

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articles as implants. In the event Applicant is arguing that the references teach away from each other, this argument is not found persuasive as the references are relied upon as alternative methods for producing porous ceramic implants and are considered teaching references where each provides motivation as stated in the previous Office Action, paper # 17 mailed 6-19-02; it would have been obvious to one skilled in the art at the time of the invention to incorporate bone cells into the invention of '013 with the motivation of using the ceramic products as artificial parts comprising growth of bone cells and the expectation that the products would be useful for inducing new-born bone, controlling resorption of bone with age, and remedying bone defects and it would have been obvious to one skilled in the art at the time of the invention to incorporate the invention of '013 into the teachings of '314 as the method of making the ceramic products and the resulting products of '013 may be made more quickly, with better mechanical strength and handling and machining characteristics.

17. Claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sambrook et al (WO 93/04013; hereafter '013) in combination with Hawley's Condensed Chemical Dictionary (1971) and further in combination with Takagi et al (US 4,654,314; hereafter '314).

'013 and '314 are relied upon for all that they teach as stated previously.

Hawley's Condensed Chemical Dictionary (1971) is relied upon for teaching that the energy required for reduction in particle size of a solid is directly proportional to the increase in surface area (Rittinger's law). In other words, the less energy results in less

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surface area and bigger particle size which would create larger pores in the same fashion as the space between large marbles in a jar is greater than the space between grains of sand in the same jar.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to decrease the heat (energy) of '013 to achieve larger pore sizes based upon '314, which teaches that the pores of the ceramic product should be between 1 and 600  $\mu\text{m}$  to promote induction of "new-born bone" and turnover of a bone while keeping a good compatibility with a living body and Hawley's which teaches that less energy results in less surface area and bigger particle size which would create larger pores.

### ***Response to Arguments***

18. Applicant's arguments filed 12-23-02 have been fully considered but they are not persuasive. Applicant's response to the rejection under 35 U.S.C. 103(a) as being unpatentable over '013 in combination with Hawley's and further in combination with '314 is based upon those arguments in response to '013 in view of '314 adding that Hawley's does not overcome the deficiencies of these references. Accordingly, the response to these arguments are again relied upon here. Since they have been set forth *supra* paragraph 16, they are not repeated here.

### ***Conclusion***

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
April 5, 2003

  
THURMAN K. PAGE  
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